

or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

§ 1140.34 Sale and distribution of non-tobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with,

those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS

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AUTHORITY: 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f; Secs. 201 and 202, Pub. L. 111-31, 123 Stat. 1776.

SOURCE: 76 FR 36753, June 22, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

- (1) Contains a health warning;
- (2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and
- (3) Is not altered by the retailer in a way that is material to the requirements of section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) or this part, including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

(d) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings in an advertisement for cigarettes if the advertisement is not created by or on behalf of the retailer and the retailer is not otherwise responsible for the inclusion of the required warnings. This paragraph shall not relieve a re-

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tailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4(b) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)), this part, or section 4(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(c)), including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

§ 1141.3 Definitions.

For the purposes of this part,

Cigarette means:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Importer means any person who imports any cigarette that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Package means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Required warning means the combination of one of the textual warning statements and its accompanying color graphic, which are set forth in “Cigarette Required Warnings,” which is incorporated by reference at § 1141.12.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term “State” includes any political division of any State.

Subpart B—Cigarette Package and Advertising Warnings

§ 1141.10 Required warnings.

(a) *Packages*. (1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings on the front and the rear panels.

(2) The required warning shall be obtained from the electronic images contained in “Cigarette Required Warn-

ings,” which is incorporated by reference at § 1141.12, and accurately reproduced as specified in “Cigarette Required Warnings.”

(3) The required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.

(4) The required warning shall be located in the upper portion of the front and rear panels of the package and shall comprise at least the top 50 percent of these panels; *Provided, however*, that on cigarette cartons, the required warning shall be located on the left side of the front and rear panels of the carton and shall comprise at least the left 50 percent of these panels.

(5) The required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(b) *Advertisements*. (1) It shall be unlawful for any manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings.

(2) The text in each required warning shall be in the English language, except that:

(i) In the case of an advertisement that appears in a non-English publication, the text in the required warning shall appear in the predominant language of the publication whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning shall appear in the same language as that principally used in the advertisement.

(3) For English-language and Spanish-language warnings, each required warning shall be obtained from the electronic images contained in “Cigarette Required Warnings,” which is incorporated by reference at § 1141.12, and accurately reproduced as specified in “Cigarette Required Warnings.”

(4) For foreign-language warnings, except for Spanish-language warnings,

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each required warning shall be obtained from the electronic images contained in “Cigarette Required Warnings,” which is incorporated by reference at § 1141.12, and accurately reproduced as specified in “Cigarette Required Warnings,” including the insertion of a true and accurate translation of the textual warning. The inserted textual warning must comply with the requirements of section 4(b)(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)(2)).

(5) The required warning shall occupy at least 20 percent of the area of each advertisement, and shall be placed in accordance with the requirements in the Federal Cigarette Labeling and Advertising Act.

(c) *Irremovable or permanent warnings.* The required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. Such warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1141.12 Incorporation by reference of required warnings.

“Cigarette Required Warnings” Edition 1.0 (June 2011), consisting of electronic files, U.S. Food and Drug Administration, referred to at § 1141.3, § 1141.10(a) and (b), and § 1141.16(a), is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, you may obtain a copy of the material by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd.,

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Rockville, MD 20850, 1-877-CTP-1373, or cigarettewarningfiles@fda.hhs.gov. You may also obtain the material at <http://www.fda.gov/cigarettewarningfiles>.

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

§ 1141.16 Disclosures regarding cessation.

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, “Cigarette Required Warnings” (incorporated by reference at § 1141.12).

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(b) In meeting the smoking cessation needs of an individual caller, the smoking cessation assistance resource required to be referenced by paragraph (a) of this section must, as appropriate:

(1) Provide factual information about the harms to health associated with cigarette smoking and the health benefits of quitting smoking;

(2) Provide factual information about what smokers can expect when trying to quit;

(3) Provide practical advice (problem solving/skills training) about how to deal with common issues faced by smokers trying to quit;

(4) Provide evidence-based advice about how to formulate a plan to quit smoking;

(5) Provide evidence-based information about effective relapse prevention strategies;

(6) Provide factual information on smoking cessation treatments, including FDA-approved cessation medications; and

(7) Provide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.

(c) The smoking cessation resource must:

(1) Other than as described in this section, not advertise or promote any particular product or service;

(2) Except to meet the particularized needs of an individual caller as determined in the context of individual counseling, not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories;

(3) Not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation;

(4) Not encourage the use of any non-evidence-based smoking cessation practices;

(5) Ensure that staff providing smoking cessation information, advice, and support are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support; and

(6) Maintain appropriate controls to ensure the criteria described in paragraphs (b) and (c) of this section are met.

(d) If the Secretary of the Department of Health and Human Services (Secretary) determines that a part of the smoking cessation assistance resource referenced by paragraph (a) of this section does not meet the criteria described in paragraphs (b) and (c) of this section, the Secretary shall take appropriate steps to address the non-compliance.

PART 1150—USER FEES

Sec.

1150.1 Scope.

1150.3 Definitions.

1150.5 Required information.

1150.7 Yearly class allocation.

1150.9 Domestic manufacturer or importer assessment.

1150.11 Notification of assessments.

1150.13 Payment of assessments.

1150.15 Disputes.

1150.17 Penalties.

AUTHORITY: 21 U.S.C. 371, 387b, 387i, 387s.

SOURCE: 79 FR 39310, July 10, 2014, unless otherwise noted.

§ 1150.1 Scope.

This part establishes requirements related to tobacco product user fees under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s). The total amount of user fees may not exceed the amount specified for that fiscal year in section 919(b) of the Federal Food, Drug, and Cosmetic Act. All domestic manufacturers and importers of tobacco products are required to pay to FDA their percentage share of the total assessment for a fiscal year.

§ 1150.3 Definitions.

The following definitions are applicable to this part:

Class of tobacco products means each of the following types of tobacco products as defined in 26 U.S.C. 5702 and for which taxes are required to be paid for the removal of such into domestic commerce: Cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.